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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALTANA PHARMA AG and WYETH, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., et al., Defendants.	Civil Action No. 04-2355 (JLL) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of Defendants' motion to dismiss Wyeth—a plaintiff in this action—from this lawsuit for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(h)(3). Defendants claim that Wyeth is neither the owner nor the true exclusive licensee of the patent-in-suit and, therefore, lacks sufficient rights in the patent to confer standing to sue for infringement. The Court has considered the submissions made in support of and in opposition to the instant motion. No oral argument was heard. Fed. R. Civ. P. 78. Based on the reasons that follow, Defendants' motion is **denied.**[1]

[1] This Court's Opinion is limited to the discrete issue of whether Wyeth has standing to sue for infringement of the patent-in-suit—that is, whether Wyeth has presented a "sufficient allegation of legal injury." *WiAV Solutions LLC v. Motorola, Inc.*, 631 F.3d 1257,1267 (Fed. Cir. 2010). This issue is separate from the question of whether Wyeth and/or Nycomed are entitled to damages for their claims of patent infringement. Thus, nothing contained herein should be construed as a substantive ruling on issues that may become relevant to Plaintiffs' request for damages or Defendants' claims of unenforceability.

BACKGROUND

1. *General*

This is a patent infringement action to enforce United States Patent No. 4,758,579 ("the '579 patent"). The asserted claims of the '579 patent – claims 22 and 25 – cover a chemical compound named Pantoprazole, and its sodium salt, pantoprazole sodium. Pantoprazole is the active ingredient in PROTONIX®, a drug manufactured for the treatment of gastric acid disorders (hereinafter referred to as "Protonix"). Plaintiff Nycomed GmbH (formerly known as Altana Pharma AG and, at the time of the invention, Byk Gulden) owns the '579 patent. Plaintiff Wyeth (formerly known as American Home Products Corporation) markets and sells Protonix in the United States as Nycomed's purported exclusive licensee.

Protonix was approved by the FDA on February 2, 2000 and was first marketed to the public in 2000. Defendants Teva,[2] Sun[3] and KUDCo each filed an Abbreviated New Drug Application ("ANDA") pursuant to the Hatch–Waxman Act, seeking FDA approval to sell a generic version of Protonix prior to the expiration of the '579 patent.

In May of 2004, Plaintiffs responded by suing Teva, Sun and KUDCo for infringement of the '579 patent. Plaintiffs' motion for a preliminary injunction was denied in September 2007. Defendants Teva and Sun subsequently launched generic pantoprazole products "at risk," i.e., before entry of final judgment on the merits of this litigation, and before the patent expired.

A jury trial was conducted for several weeks in April 2010 with respect to Defendant Teva and Defendant Sun's affirmative defenses and counterclaims that Claims 22 and 25 of the '579 patent are invalid for obviousness and obviousness-type double patenting. Simultaneously,

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[2] Teva's ANDA was filed on or about April 6, 2004.

[3] Sun filed its ANDA on or about March 1, 2005, and June 25, 2005.

a non-jury trial was conducted with respect to Defendant KUDCo's affirmative defenses and counterclaims. The jury returned a verdict in favor of Plaintiffs as to each issue tried. On July 15, 2010, the Court issued a bench opinion as to Defendant KUDCo. The Court ruled that KUDCo had not demonstrated by clear and convincing evidence that the asserted claims of the '579 patent are invalid either for obviousness under 35 U.S.C. § 103 or under the judicially created doctrine of obviousness-type double patenting. The parties subsequently began discovery on the remaining issues in the case—damages and Defendants' claims of unenforceability.

The '579 patent expired on July 19, 2010. The FDA awarded Wyeth a period of pediatric exclusivity that expired on January 19, 2011.

2. *Defendants' Motion*

Defendants Teva and Sun now move to dismiss Wyeth from this lawsuit for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(h)(3) on the basis that Wyeth—which is, according to Defendants, neither the owner nor the true exclusive licensee of the patent-in-suit—does not have sufficient rights in the patent-in-suit to have standing. In particular, Defendants maintain that although Wyeth's standing in this action was premised on its alleged role as the exclusive licensee of the patent-in-suit, several important restrictions on the rights Nycomed granted to Wyeth under the parties' License Agreement prevent Wyeth from having the exclusive rights necessary to confer standing. Defendants maintain that three (3) restrictions, in particular, should control the question of standing:

First, according to Defendants, Wyeth's rights under the License Agreement were limited to the sale of ***branded*** pantoprazole products under the Protonix trademark. Because Wyeth did

not have any right to sell pantoprazole in the generic form at the time the action was commenced, Wyeth lacked an exclusionary right with respect to the infringement alleged in this case.

Second, Defendants maintain that any "exclusive" rights granted by Nycomed to Wyeth were illusory because the License Agreement only provides Wyeth with the right to manufacture and sell ***finished*** pharmaceutical products; as a result, Nycomed could nullify Wyeth's "exclusive" rights at any time simply by licensing another party to make, use or sell pantoprazole ***compound***.

Third, according to the Defendants, the License Agreement strictly limited Wyeth's exclusive rights to the field of prescription pharmaceutical products. Because Nycomed expressly retained the right to license other companies to make, use and sell over-the-counter ("OTC") pantoprazole products, which—according to Defendants—could compete directly with their prescription equivalents, Wyeth had no real enforceable promise that it would be free from competition in the market of prescription pharmaceutical products.

3. *The Parties' License Agreement*[4]

The License Agreement was signed by Byk Gulden (Nycomed) in December 1996 and countersigned by American Home Products Corporation (Wyeth) in January 1997. (W00532232). The License Agreement, which has since been amended several times, grants Wyeth certain rights in Nycomed patents, including the '579 Patent (referred to therein as the "Substance Patent"), subject to various terms and conditions, the most relevant of which are set forth below:

[4] A copy of the parties' License Agreement is attached as Exhibit 32 to the Declaration of Matthew M. Hoffman, submitted by Defendants, and as Exhibit 38 to the Declaration of Hector D. Ruiz, submitted by Plaintiffs.

2.2.1	Grant of License (W00532175)	Subject to all terms and conditions of this Agreement [Nycomed] hereby grants and [Wyeth] hereby accepts for the term hereinafter specified an exclusive license under the Patents, wherever applicable, and Know-how of [Nycomed], limited to the Field[5] in the Territory.[6] Notwithstanding anything above to the contrary, [Nycomed] retains the right, for itself or its Affiliates only to market, use and sell a generic non-branded prescription version of the Product in the Territory after Substance Patent expiry.
2.2.1.2	Manufacture (W00532175)	to Manufacture[7] Products[8] subject to the provisions of this agreement relating to the supply of Primary Products.[9]
2.2.1.3	Marketing and Sales (W00532175)	to market, use and sell Products under the Trademarks in the Territory; further, to market, use and sell a generic, non-branded prescription version of the Products in the Territory after Substance Patent expiry.
2.2.4	Exclusivity of License (W00532177)	The term exclusive license as used herein shall mean that only [Wyeth] and/or subject to the provisions of this Agreement, its sub-licensee shall be entitled to exercise the rights granted hereunder except as provided in Section 2.2.1 of this Agreement.
2.2.8	Construction of License (W00532177)	Nothing in this Agreement shall be construed as giving [Wyeth] any right to use or otherwise deal with [Nycomed's] Patents, Know-how and Information for purposes other than those of Development, Manufacturing, marketing and selling Products under the Trademark in the Field and Territory during the term of

[5] "Field" is defined, in Article 1.14, as "the area of prescription sales for all human pharmaceutical uses to the exclusion of non-prescription." (W00532171).

[6] "Territory" is defined, in Section 1.36, as "the United States of America, its territories and possessions and the Commonwealth of Puerto Rico" (W00532174).

[7] "Manufacture" is defined, in Section 1.25, as "the converting of Primary Products, in particular Compound or bulk tablets, supplied by [Nycomed] or . . . [Nycomed's] appointee, into finished Products" (W00532173).

[8] "Products" is defined, in Section 1.32, as "any and all finished pharmaceutical specialties containing the Compound, alone or in combination with other active ingredients." (W00532174).

[9] "Primary Products" is defined, in Section 1.31, as "the Compound or semi-finished Products required for the Manufacture of the Products in packaged pharmaceutical form, including but not limited to bulk tablets." (W00532174).

		this Agreement as specified herein.
2.3.1	Option Right (W00532177)	[Nycomed] grants and [Wyeth] accepts an exclusive option right to exclusively license the Compound and Products in the Field under the Patents, the Know-how and a Trademark of [Nycomed] in the Territory for non-prescription (Over-the-Counter) sales . . .
5.3	Holder of Registration	The registration of Products by the FDA shall be made by and in the name of [Wyeth] as registration holder; Products shall be registered under [Nycomed's] Trademarks . . . .
7.2.3	[Wyeth's] Right to Take Legal Action (W00532187)	In the event that, after being requested by [Wyeth] to take steps to terminate any case of alleged infringement, [Nycomed] fails either to terminate the same or to bring legal action against the alleged infringer . . . [Wyeth] shall have the right at its own expense . . . to take such steps, to bring suck action, or to prosecute an action already brought. To the extent legally necessary, [Wyeth] may assert the Patents in the name of [Nycomed].
9.1.1	Use of Trademark License Granted hereunder (W00532192)	Subject to the right granted to [Wyeth] under Art. 2.2.1.3 to market, use and sell a generic, non-branded Rx version of the Product in the Territory after Substance Patent expiry, the Trademark license granted under Art. 2.2.1.3 means that [Wyeth] shall distribute, market and sell the Products in the Territory only under the Trademarks and that [Wyeth] agrees to use the Trademarks only in connection with the Products in the Territory.
12.2.3	Supplies of Primary Products and Products (W00532199-W00532200)	Beginning with the time when [Wyeth] starts purchasing Primary Products, in particular, Compound, from Third Parties manufacturing the Compound, or manufacturing the Compound by itself, [Nycomed] shall be under no obligation to supply [Wyeth] with Primary Products including Compound with the exception of firm orders of [Wyeth] acknowledged by [Nycomed] at the time when [Wyeth] starts such Third Party purchases or its own manufacturing. Likewise, [Nycomed] shall be entitled to supply Third Parties with Primary Products including Compound when [Wyeth] starts such Third Party purchases.

Following Teva's generic launch in December 2007, on January 29, 2008, Nycomed and Wyeth entered into the Panto Generic Letter Agreement.[10] The Panto Generic Letter Agreement permitted Wyeth to manufacture and sell generic pantoprazole tablets prior to the expiration of the '579 Patent. The Panto Generic Letter Agreement provides, in pertinent part:

> Following the denial of Plaintiff's motion for a preliminary injunction and after receiving FDA approval of its generic pantoprazole product, Teva launched in the Territory its generic pantoprazole product "at risk" on December 21, 2007, and has indicated its intent to sell more product. Sun has indicated its intent to launch its generic pantoprazole product, also "at risk," in the Territory. In light of these developments, the Parties acknowledge that in response to the actions of Teva and/or Sun, and given the resulting damage to the Protonix product, it is commercially desirable that Wyeth and [Nycomed] be able to launch their own generic pantoprazole product.
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> Wyeth and [Nycomed] agree that Wyeth had and continues to have an exclusive license under the relevant Patents to manufacture (based on Compound supplied by [Nycomed]) and commercialize the Product in the Territory and . . . may . . . manufacture and commercialize in the Territory prior to the Substance Patent expiry, a generic prescription version of the 40mg Product and the 20 mg Product . . .

(W05598917).

Finally, in April 2009, the parties entered into the "Ninth Amendment" to the License Agreement which amended, *inter alia*, Section 2.2.1.3 of the License Agreement ("Marketing and Sales") by granting Wyeth the right to "market, use and sell Non-Branded Generic Rx Product in the Territory and in the Field in accordance with the Panto Generic Letter Agreement (as amended by this Ninth Amendment) during the term thereof and thereafter . . . ." (Ruiz Decl., Ex. 69, ¶ 3.1.2) (W03541293).

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[10] A copy of the Panto Generic Letter Agreement is attached as Exhibit 17 to the Hoffman Declaration, and as Exhibit 67 to the Ruiz Declaration.

LEGAL STANDARD

Article III of the United States Constitution limits the judicial power of federal courts to resolution of actual "cases" and "controversies." U.S. Const. art. III, § 2. Constitutional standing requires that a plaintiff adequately establish:

> (1) an injury in fact (i.e., a concrete and particularized invasion of a legally protected interest); (2) causation (i.e., a fairly traceable connection between the alleged injury in fact and the alleged conduct of the defendant); and (3) redressability (i.e., it is likely and not merely speculative that the plaintiff's injury will be remedied by the relief plaintiff seeks in bringing suit).

Sprint Commc'ns Co., L.P. v. APCC Servs., 554 U.S. 269, 273 (2008) (internal quotations omitted); *Evident Corp. v. Church & Dwight Co., Inc.*, 399 F.3d 1310, 1313 (Fed. Cir. 2005).

The dispute raised in Defendants' motion concerns the element of injury in fact. In the context of patent cases, injury in fact occurs when the patentee's exclusionary rights are violated. *See WiAV Solutions LLC v. Motorola, Inc.*, 631 F.3d 1257, 1265 (Fed. Cir. 2010); *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1339 (Fed. Cir. 2007). Thus, only a patent owner or an exclusive licensee can have constitutional standing to bring an infringement suit; a non-exclusive licensee does not. *Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005) ("A nonexclusive license confers no constitutional standing on the licensee to bring suit or even to join a suit with the patentee because a nonexclusive licensee suffers no legal injury from infringement.") (internal citations omitted); *see, e.g., Evident Corp. v. Church & Dwight Co., Inc.*, 399 F.3d 1310, 1314 (Fed. Cir. 2005).

In order to be considered an exclusive licensee for purposes of standing, "a party must have received, not only the right to practice the invention within a given territory, but also the patentee's express or implied promise that others shall be excluded from practicing the invention within that territory as well." *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1552 (Fed. Cir.

1995). The determination of whether "a licensee is an exclusive licensee or a bare licensee is a question of ascertaining the intent of the parties to the license as manifested by the terms of their agreement and examining the substance of the grant." *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998). "The use of the word 'exclusive' is not controlling; what matters is the substance of the arrangement." *Id.*

The issue of constitutional standing is jurisdictional; thus, it cannot be waived and can be raised at any stage of the litigation. *See, e.g., Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, 320 F.3d 1354, 1367 (Fed. Cir. 2003). Standing is determined as of the date an action is filed. *See, e.g., Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359, 1364 (Fed. Cir. 2010) ("A court may exercise jurisdiction only if a plaintiff has standing to sue on the date it files suit.").

Finally, the Court notes that Defendants motion is brought pursuant to Federal Rule of Civil Procedure 12(h)(3). "[A] dismissal based on lack of subject matter jurisdiction goes to 'the trial court's . . . very power to hear the case.' [Thus], no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Burg v. U.S. Dep't of Health & Human Servs.*, 387 Fed. Appx. 237, 239 (2010) (internal quotations omitted). With this framework in mind, the Court turns now to Defendants' motion.

ANALYSIS

1. *Wyeth Has Constitutional Standing*

"The touchstone of constitutional standing in a patent infringement suit is whether a party can establish that it has an exclusionary right in a patent that, if violated by another, would cause the party holding the exclusionary right to suffer legal injury." *WiAV,* 631 F.3d at 1265.

The Court begins its analysis by making the following relevant findings: (1) pursuant to the *express* terms of the 1996 License Agreement, Nycomed provided Wyeth with the exclusive right, under the '579 patent, to manufacture and sell prescription pantoprazole in the United States during the period of patent exclusivity,[11] (2) the License Agreement contains no reservation of rights for any other licensee in Wyeth's exclusive field of use (that is, the marketing and sales of prescription pantoprazole in the United States during the period of patent exclusivity),[12] (3) in April 2004, Defendant Teva filed an Abbreviated New Drug Application seeking FDA approval to sell a generic version of Protonix *prior* to the expiration of the '579 patent,[13] and (4) in May of 2004, and before patent expiry, Plaintiffs responded by suing Teva for infringement of the '579 patent.[14] In light of the foregoing, the Court finds that Wyeth has sufficiently demonstrated for purposes of this motion that: (a) it held certain significant rights to the '579 patent—including the exclusive right to sell prescription pantoprazole in the United States during the life of the patent; (b) the License Agreement contained an express promise that others shall be excluded from practicing the invention within that territory;[15] and (c) Wyeth

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[11] *See* License Agreement Sections 2.2.1, 2.2.1.2, 2.2.4, 2.2.1.3.

[12] *See* Section 2.2.1. By contrast, Nycomed *did* expressly retain the right, "for itself," to "market, use and sell a generic non-branded prescription version of the Product in the Territory after Substance Patent expiry." *Id.*

[13] *See Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1004 (Fed. Cir. 2009) ("On or about April 6, 2004, Teva filed an Abbreviated New Drug Application ("ANDA") pursuant to the Hatch–Waxman Act, requesting FDA approval to sell a generic version of Protonix ® prior to the expiration of the '579 patent. Sun filed similarly directed ANDA applications on or about March 1, 2005, and June 25, 2005."); *Altana Pharma AG v. Teva Pharms., USA, Inc.*, 532 F. Supp. 2d 666, 671 (D.N.J. 2007).

[14] *See Altana,* 566 F.3d at 1004 ("Following the submission of these ANDA applications, Nycomed filed suit against Teva and, subsequently, against Sun.").

[15] *See* License Agreement Sections 2.2.1, 2.2.4.

sustained injury by virtue of Defendants' alleged infringement—*i.e.*, its sale of prescription pantoprazole during the life of the patent.[16] The Court's analysis on the issue of standing need go no further. *See Evident,* 399 F.3d at 1313 ("Constitutional standing requires only that a plaintiff must have suffered an injury in fact, that there be a causal connection between the injury and a defendant's conduct, and that the injury be redressable by a favorable court decision."); *cf. Davis v. Passman,* 442 U.S. 228, 239 n. 18 (1979) (explaining that the question of whether a party has standing to sue is separate from the question of whether the party has a cause of action).

These factors differentiate the circumstances of this case from those cases in which the Federal Circuit has found a lack of constitutional standing as to a purported exclusive licensee. *See, e.g., Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc., 620 F.3d 1305, 1318* (Fed. Cir. 2010) (finding lack of standing where "SSI fails to point to any evidence other than its current [corporate] 'organization' to show that Synthes Spine is an exclusive licensee" and noting that "the fact that Synthes Spine is currently the only entity practicing the '071 patent does not mean that SSI has promised to exclude all others from doing so."); *Bicon, Inc. v. Straumann Co.,* 441 F.3d 945, 956 (Fed. Cir. 2006) (finding lack of standing where "the only evidence Bicon cites in support of its contention that its license was exclusive is the testimony of its president, Dr. Vincent Morgan. Dr. Morgan testified that Bicon's right to practice the patent was 'exclusive at the moment,' but he promptly explained that Bicon's right to practice the patent was 'exclusive' only in the sense that Bicon was the only licensee of the Diro patent at the

[16] *See, e.g.,* Ruiz Decl., Ex. 67, Panto Generic Letter Agreement at 1-2 ("In light of these developments, the Parties acknowledge that in response to the actions of Teva and/or Sun, and given the resulting damage to the Protonix product, it is commercially desirable that Wyeth and Nycomed be able to launch their own generic pantoprazole product.").

time."); *Rite-Hite,* 56 F.3d at 1553 (finding no constitutional standing where putative exclusive licensee "had no right under the agreements to exclude anyone from making, using, or selling the claimed invention," "could not exclude from their respective territories other ISOs, third parties, or even Rite–Hite itself," and where "any remedy [it] might have had for violation of its rights would lie in a breach of contract action against Rite–Hite, if the agreement was breached, not in a patent infringement action against infringers.").

2. *Defendants Arguments are Unavailing*

The Court has carefully considered the remaining arguments raised by Defendants and, based on the reasons that follow, finds them to be both unavailing and beyond the scope of this motion.

A. *The Purported Trademark Limitation*

Defendants argue that the license granted to Wyeth simply gave it the exclusive right to make and sell *branded* prescription pantoprazole—not the generic prescription pantoprazole that Defendants ultimately sold. In support of this position, Defendants rely predominately on Section 2.2.1.3 ("Marketing and Sales") which provides that Nycomed hereby grants to Wyeth the exclusive license "to market, use and sell Products *under the Trademarks* in the Territory; further, to market, use and sell a generic, non-branded prescription version of the Products in the Territory after Substance Patent expiry." (W00532175) (emphasis added). According to Defendants, "the natural and logical interpretation of this provision permits only one conclusion: the patent license granted in Section 2.2.1 is limited to the marketing and sale of branded products (i.e., products sold 'under the Trademarks')." (Def. Br. at 7).

State law governs contract interpretation. *See Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1369 (Fed. Cir. 2004). Thus, the law of the state of New Jersey governs the License Agreement. Under New Jersey law, it is "well-settled . . . that when the terms of a contract are clear, 'it is the function of a court to enforce it as written and not to make a better contract for either of the parties.' " *CSFB 2001–CP–4 Princeton Park Corporate Ctr., LLC v. SB Rental I, LLC*, 410 N.J. Super. 114, 120 (App. Div. 2009) (quotation omitted). Thus, "[a]bsent ambiguity, the intention of the parties is to be ascertained by the language of the contract." *Id.*

Having carefully considered the parties' arguments concerning the meaning, relevance and implications of Section 2.2.1.3, the Court finds the language of said Section to be ambiguous. Its ambiguity is highlighted when read in conjunction with other provisions of the License Agreement. For example, the Preamble to the License Agreement explains, by way of background, that Nycomed granted Wyeth an "exclusive option to an exclusive license to market and sell Pantoprazole in the United States provided that the parties succeeded in lifting the clinical hold on the [Investigational New Drug] application for Pantoprazole." (W00532169). The Preamble goes on explain that "[b]ecause the combined efforts of the parties have proven successful, [Wyeth] has exercised this option" by entering into the License Agreement. (*Id.*). The Preamble does not limit Wyeth's "exclusive option to an exclusive license to market and sell Pantoprazole" to *branded* pantoprazole.

Similarly, Section 2.2.1 grants Wyeth "an exclusive license under the Patents" limited to the "area of prescription sales for all human pharmaceutical uses" in the United States, its territories and Puerto Rico, and does not contain the purported "under the Trademarks" limitation. *See* Sections 2.2.1, 1.14, 1.36. Section 2.2.1 goes on to provide that "[n]otwithstanding anything above to the contrary, [Nycomed] retains the right, for itself or its

Affiliates only to market, use and sell a generic non-branded prescription version of the Product in the Territory after Substance Patent expiry." If the Court were to accept Defendants' interpretation that the license granted to Wyeth is limited to *branded* pantoprazole during the life of the patent, then the foregoing provision would be meaningless. Stated differently, Nycomed would have had no reason to clarify its right to introduce a generic post-expiry *if*—pursuant to the License Agreement—it had retained the right to do so before the patent expired.

Finally, the Court notes that testimony by a Nycomed witness supports the interpretation that, during the period of exclusivity, Nycomed did not retain the right to market or sell generic pantoprazole. *See* Ruiz Decl., Ex. 38, Passet Tr. 159-160 ("during the time of – of exclusivity, there was no right of Nycomed either of Byk – Byk Gulden to enter into the market").

In light of the foregoing evidence, the Court draws two conclusions: (1) the parties did *not* specifically intend to limit the license granted to Wyeth to branded pantoprazole, and (2) the parties did not contemplate or expressly address the possibility or implications of competition from an infringing generic pantoprazole product during exclusivity at the point in time when they entered into the License Agreement;[17] thus, any ambiguities or silence on the issue of Wyeth's rights *vis-à-vis* generic (or non-branded) pantoprazole during exclusivity should not be interpreted, for purposes of the instant motion, as a limitation on Wyeth's "exclusive license under the Patents." (W00532175).

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[17] *See, e.g.,* Ruiz Decl., Ex. 67, Panto Generic Letter Agreement at 2 ("Following the denial of Plaintiffs' motion for a preliminary injunction . . . Teva launched in the Territory its generic pantoprazole product "at risk" . . . . . Sun has indicated its intent to launch its generic pantoprazole product also "at risk," in the Territory. In light of these developments, the Parties acknowledge that in response to the actions of Teva and/or Sun, and given the resulting damage to the Protonix product, it is commercially desirable that Wyeth and Nycomed be able to launch their own generic pantoprazole product.").

B. *Wyeth's Rights Vis-à-vis Pantoprazole Compound*

Next, Defendants argue that, pursuant to the doctrine of patent exhaustion, Wyeth's rights in the Field of the Finished Product are illusory because Nycomed could, at any time, nullify them by licensing another party to make, use and/or sell pantoprazole *compound*—the substance that is actually disclosed in the patent.

"The longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item." *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 625 (2008). According to Defendants, "*if* Nycomed licensed another party to make, use and sell pantoprazole compound (as it is free to do under the terms of the [License] Agreement) then Wyeth *could* face competition" (Def. Br. at 22) (emphasis added). Thus, according to Defendants, Wyeth cannot meet the basic requirements of *Rite-Hite* because it had no right to practice the patented invention—*i.e,* to make, use and sell pantoprazole compound—and it has no promise from Nycomed that others would be excluded from doing so. *See Rite-Hite,* 56 F.3d at 1552. The Court finds Defendants' argument in this regard far too speculative, both legally and factually, for several reasons.

First, the Court finds that, pursuant to the License Agreement, Nycomed did *not* retain the unilateral right to license to others the ability to make, use and/or sell pantoprazole compound. Section 12.2.1 of the License provides:

> For the Initial Term of this Agreement, [Nycomed] undertakes to exclusively supply to [Wyeth] and [Wyeth] undertakes to exclusively purchase from [Nycomed] all of [Wyeth's] requirements of Primary Products (Compound, or, of [sic] so agreed upon, bulk tablets) and, if so agreed upon, Products, as the case may be.

(W00532199). Section 12.2.3 goes on to provide that Nycomed was not authorized to supply any other parties with compound *until* such time as Wyeth exercised its right to source the compound from third parties. This section states:

> Beginning with the time when [Wyeth] starts purchasing Primary Products, in particular Compound, from Third Parties manufacturing the Compound, or manufacturing the Compound by itself, [Nycomed] shall be under no obligation to supply [Wyeth] with Primary Products including Compound . . . Likewise, [Nycomed] shall be entitled to supply Third Parties with Primary Products including Compound when [Wyeth] starts such Third Party purchases.

(W00532199-W00532200). Thus, the Court finds that, pursuant to the License Agreement, Wyeth received not only the right to practice the invention within a given territory—including the right to make, use and sell prescription pantoprazole by purchasing the compound from Nycomed—but also the patentee's express promise that others—including itself—shall be excluded from practicing the invention within that territory, so long as Wyeth did not elect to purchase the compound from a third-party.

Second, even accepting Defendants' interpretation of Wyeth's rights *vis-à-vis* pantoprazole compound, Defendants fail to convince the Court that the doctrine of patent exhaustion, applied to the *hypothetical* presented by Defendants,[18] would warrant dismissal of Wyeth on the basis of lack of standing. For instance, Defendants do not argue that they actually *did* purchase pantoprazole compound from Nycomed (or any other licensee) or that Nycomed actually *did* license to any other party the right to sell pantoprazole compound, much less to anyone other than Wyeth. Thus, without more, Defendants have failed to convince the Court that

[18] *See* Def. Br. at 22 ("*If* Nycomed licensed another party to make, use and sell pantoprazole compound (as it is free to do under the terms of the [License] Agreement) then Wyeth *could* face competition") (emphasis added).

the doctrine of patent exhaustion is even applicable. *See, e.g., Powertech Tech. Inc. v. Tessera, Inc.*, 660 F.3d 1301, 1304 (Fed. Cir. 2011) (finding doctrine of patent exhaustion applicable where infringer had actually purchased all of its products from licensed subcontractors); *Tessera, Inc. v. Int'l Trade Comm'n*, 646 F.3d 1357, 1370 (Fed. Cir. 2011) (applying doctrine of patent exhaustion where certain licensees were expressly authorized to and ultimately did sell the accused products).

In any event, the relevant question is not whether Wyeth has established that it has the right to exclude *all* others from practicing the '579 patent, but whether Wyeth has shown that it has the right under the '579 patent to exclude Defendants from engaging in the alleged infringing activity.[19] *See, e.g., WiAV,* 631 F.3d at 1267. Stated differently, whatever the merits of Defendants' hypothetical concerning the provision of pantoprazole compound, "to have standing to sue the Defendants at this point in the proceedings [Wyeth] . . . need only present a sufficient allegation of legal injury." *Id.* As previously stated, the Court finds that Wyeth has made this showing pursuant to, *inter alia*, the express terms of the License Agreement.[20] Defendants' argument is therefore rejected.

C. *Wyeth's Rights Vis-à-vis Non-Prescription Pantoprazole*

Lastly, Defendants argue that Wyeth is not truly an exclusive licensee for standing purposes because the License Agreement contained a carve-out for over-the-counter ("OTC")

[19] Defendants do not challenge Wyeth's ability to show that it was injured by virtue of Defendants' conduct. *See, e.g., WiAV*, 631 F.3d at 1267 ("The question is whether WiAV has shown that it has the right under the patents to exclude the Defendants from engaging in the alleged infringing activity and therefore is injured by the Defendants' conduct.").

[20] *See* License Agreement Sections 2.2.1, 2.2.4, 2.2.1.3.

pantoprazole. In particular, Defendants theorize that Wyeth could not legitimately expect to be free from competition in the sales of finished products containing pantoprazole compound because: (a) Nycomed retained the right to sell or license to others an OTC pantoprazole product, and (b) OTC products compete directly with their prescription-only counterparts. Again, based on the reasons that follow, the Court finds that this argument—which is based on nothing more than a hypothetical—goes beyond the limited scope of this motion.

As a general matter, the Court agrees that, pursuant to the License Agreement, Wyeth was not granted the exclusive right to market or sell non-prescription (or, OTC) pantoprazole. *See* Article 2.2.1 ("Nycomed] hereby grants and [Wyeth] hereby accepts for the term hereinafter specified an exclusive license under the Patents, wherever applicable, and Know-how of [Nycomed], limited to the Field[21] in the Territory"); 1.14 (defining Field as "the area of prescription sales for all human pharmaceutical uses to the exclusion of non-prescription.").[22] Whatever importance Defendants' attribute to this carve-out is rendered meaningless, however, given Defendants' concession that "pantoprazole has not yet been sold in OTC form in the United States." *See* Def. Br. at 12-13; Pl. Opp'n Br. at 5 n. 4 ("No OTC license was ever entered, nor was an OTC pantoprazole product ever introduced in the United States.").

In any event, as previously stated, the *sole* issue before the Court on Defendants' motion to dismiss Wyeth for lack of constitutional standing is whether Wyeth has shown that it has (or

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[21] "Field" is defined, in Section 1.14, as "the area of prescription sales for all human pharmaceutical uses to the exclusion of non-prescription." (W00532171).

[22] It is undisputed that Wyeth did not exercise its "exclusive option" to launch an OTC pantoprazole product. *See* Section 2.3.1 ("[Nycomed] grants and [Wyeth] accepts an exclusive option right to exclusively license the Compound and Products in the Field under the Patents, the Know-how and a Trademark of [Nycomed] in the Territory for non-prescription (Over-the-Counter) sales . . ."); Hoffman Decl., Ex. 5 (Passet Dep.) at 160-162.

had) the right, under the '579 patent, to exclude Defendants from engaging in the alleged infringing activity—*i.e.,* the sale of prescription pantoprazole in the United States during patent exclusivity—and therefore was injured by virtue of Defendants' conduct. *See WiAV*, 631 F.3d at 1267. For all of the reasons set forth above, the Court concludes that Wyeth, in its capacity as exclusive licensee of the '579 patent,[23] has satisfied this standard.

CONCLUSION

For the reasons set forth above, Defendants' motion to dismiss Wyeth for lack of standing [Docket Entry No. 1135] is **denied.**

An appropriate Order accompanies this Opinion.

DATED: October 11, 2012

s/ Jose L. Linares
Jose L. Linares
United States District Judge

[23] The Court's finding in this regard is in line with: (1) the parties' Proposed Findings of Fact and Conclusions of Law, *see* Docket Entry No. 835, ¶ 32; Docket Entry No. 846, ¶ 32; and (2) this Court's July 15, 2010 Opinion which stated that "Plaintiff Wyeth markets and sells Protonix in the United States as Nycomed's exclusive licensee," *see* Docket Entry No. 879 at 1.